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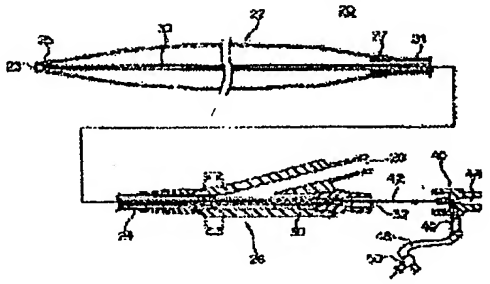
(54) BALOON CATHETER

(57)Abstract:
PURPOSE: To provide a baloon catheter for measurement of blood pressure, wherein a catheter withstands the force-back action by blood flow and a catheter does not cause the body kink after insertion into blood vessel.
CONSTITUTION: A baloon catheter 20 of the disclosure is composed of a baloon 22 having the auxiliary activity for cardiac function in aorta by expanding and contracting action, a catheter tube 24 through which a pressurized fluid can be introduced and discharged for the baloon action, a flexible inner tube 30 which is extending along longitudinal direction passing through a catheter tube 24 and a baloon end 22 where a tube 30 is connected to a blood liaison unit 23. At the other tip of a catheter tube 24, a connecter 26 is installed, where a gateway 28 for the pressurized fluid and a measurement unit 32 are devised. A metallic stylet 42 is passed through a flexible inner tube 30 from a unit 32 towards a blood liaison unit 23 after insertion of a catheter into blood vessel.



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CLAIMS

[Claim(s)]
[Claim 1]A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed, A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part, It is open for free passage to a blood communicating hole established in a tip part of said balloon part, and said balloon part and an inside of a catheter tube so that it may not be open for free passage with a channel of a pressure fluid, A flexible inner tube which extends in shaft orientations, and a pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A balloon catheter which has a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and a metal stylette pipe inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.
[Claim 2]The balloon catheter according to claim 1 after a balloon part and a catheter tube are inserted said stylette pipe into a blood vessel, wherein it is inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.
[Claim 3]The balloon catheter according to claim 1 or 2 which has a flash means which supplies a fluid for preventing coagulation of a blood flow in a crevice between said stylette pipe and said flexible inner tube.
[Claim 4]A balloon catheter comprising:
A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed.
A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part.
A flexible inner tube which extends in shaft orientations so that it may be open for free passage to a blood communicating hole established in a tip part of said balloon part and said balloon part and an inside of a catheter tube may not be opened for free passage with a channel of a pressure fluid.
A pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A wire rod for blood pressure measurement which has a pressure sensor at a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and a tip inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.

[Claim 5]The balloon catheter according to claim 4 after a balloon part and a catheter tube are inserted said wire rod for blood pressure measurement into a blood vessel, wherein it is inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.
[Claim 6]The balloon catheter according to claim 4 or 5 which has a flash means which supplies a fluid for preventing coagulation of a blood flow in a crevice between said wire rod for blood pressure measurement, and said flexible inner tube.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Industrial Application]This invention relates to the balloon catheter used for the balloon pumping method in a main artery which are cures, such as acute cardiac insufficiency.
[0002]
[Description of the Prior Art]The balloon pumping method in a main artery (Intra-aortic balloon pumping and the following call it the "IABP method" for short), For the therapy at the time of the cardiac performance fall of cardiac insufficiency etc., as shown in drawing 6, the balloon catheter 2 which comprises synthetic macromolecule material in a main artery is inserted, It is an auxiliary cycle method which doubles with the pulsation of the heart 1, introduces or draws a pressure fluid from the catheter tube 6 to the balloon part 4 with the pumping plant 8, expands and shrinks the balloon part 4, and assists cardiac performance.
[0003]As a balloon catheter used for the IABP method, the balloon catheter as shown in JP,S63-206255,A and JP,S62-114565,A is known. In such a balloon catheter, in order to double with the pulsation of the heart and to expand and contract a balloon part, it is necessary to detect the pulsation of a patient's heart. As a means to detect the pulsation of a patient's heart, the body surface or inside of a patient is equipped with an electrode, and there is a means to detect the pulsation of the heart as an electrical signal.
[0004]As a means to detect the pulsation of the heart from a patient's blood pressure using a balloon catheter, There is a method of detecting the pulsation of the heart by establishing a blood communicating hole in the end chip part 12 of the balloon part 4 shown in drawing 6, making shaft orientations insert the blood communicating hole and the inner tube 10 open for free passage in the balloon part 4 and the inside of the catheter tube 6, and measuring blood-pressure change from a blood communicating hole.
[0005]When inserting the balloon part 4 and the catheter tube 6 into a patient's arterial blood pipe, a guide wire is inserted into the inner tube 10, and a balloon catheter is inserted along with it. The inner tube 10 also has a function as a guide rod in the case of insertion with a guide wire. Therefore, the inner tube 10 needs to have a certain amount of rigidity. Since a balloon catheter is inserted into the blood vessel of the patient who wound, the inner tube 10 needs to have a certain amount of pliability.
[0006]If the rigidity of the inner tube 10 is too high, while having inserted in the balloon catheter in a patient's blood vessel, it is not desirable from there being a possibility of damaging a patient's blood vessel. If the pliability of the inner tube 10 is too high conversely, when the balloon part 4 will be located in the artery near the pole of the heart 1 and an auxiliary operation of the heart will be performed, It is not desirable from a blood flow **** (ing), and being unable to perform pumping of the balloon part 4 in a regular position, but there being a possibility that an auxiliary operation of the heart may fall, and there being a possibility of blockading the renal artery which branches from an abdominal aorta. It is important for the balloon part 4 to make it located as much as possible in the arterial blood pipe near the heart, and to perform a pumping action.
[0007]From such a viewpoint, a resin tube, a small tube made from stainless steel, etc. which were reinforced with a mesh are used as the conventional inner tube 10.
[0008]
[Problem(s) to be Solved by the Invention]However, the balloon catheter which has merits and demerits, respectively and is simultaneously satisfied with the balloon catheter using such a conventional inner tube 10 of the insertion nature into the blood vessel which wound, and the rigidity which does not **** to a blood flow and a kink (break) etc. do not produce was called for.
[0009]Measurement of the blood pressure in the blood vessel in which it is made in view of such the actual condition, and a balloon catheter is inserted is possible for this invention, And insertion into the blood vessel which wound is easy, and is not ****(ed) by the blood flow etc. after insertion, but it aims at providing the balloon catheter which a kink (break) etc. do not produce.

[0010]
[Means for Solving the Problem]To achieve the above objects, a balloon catheter of this invention is provided with the following.
A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed.
A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part.
A flexible inner tube which extends in shaft orientations so that it may be open for free passage to a blood communicating hole established in a tip part of said balloon part and said balloon part and an inside of a catheter tube may not be opened for free passage with a channel of a pressure fluid.
A pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A metal stylette pipe inserted in a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.

[0011]A balloon catheter concerning another viewpoint of this invention is provided with the following.
A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed.
A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part.
A flexible inner tube which extends in shaft orientations so that it may be open for free passage to a blood communicating hole established in a tip part of said balloon part and said balloon part and an inside of a catheter tube may not be opened for free passage with a channel of a pressure fluid.
A pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A wire rod for blood pressure measurement which has a pressure sensor at a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and a tip inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.

[0012]
[Function]When inserting the balloon catheter of this invention into a blood vessel, a balloon catheter is inserted into a blood vessel in the state where a metal stylette pipe or wire rod for blood pressure measurement is not inserted into a flexible inner tube. Therefore, it excels in flexibility, and as for a balloon catheter, the inside of the blood vessel which wound can be inserted good, without damaging a blood vessel wall.
[0013]After inserting a balloon catheter, a stylette pipe or the wire rod for blood pressure measurement is inserted along with a flexible inner tube from the measuring aperture currently formed in the connector. The tip of a stylette pipe or the wire rod for blood pressure measurement reaches to the end chip part of a balloon part along with the inside of a flexible inner tube. Therefore, a patient's blood can be drawn outside of the body through the inside of a stylette pipe, and the blood-pressure change can be measured. To the tip part of the wire rod for blood pressure measurement, since the pressure sensor is attached, a direct patient's blood-pressure change can be measured with the pressure sensor.
[0014]And a metal stylette pipe and wire rod for blood pressure measurement, Since rigidity is high as compared with a flexible inner tube, by inserting these any they are into a flexible inner tube, the rigidity of a balloon catheter improves, a possibility that a balloon catheter may be ****(ed) by the blood flow decreases, and a kink (break) can also be prevented effectively.
[0015]
[Example]Hereafter, the balloon catheter concerning this invention is explained in detail based on working example shown in Drawings. The outline sectional view of the balloon catheter which requires drawing 1 for one working example of this invention, the fragmentary sectional view in which drawing 2 shows the important section of the balloon catheter of the working example, The fragmentary sectional view in which drawing 3 shows the important section of others of the working example, the partial fracture perspective view of the wire rod for blood pressure measurement used for the balloon catheter which requires drawing 4 for other working example of this invention, and drawing 5 are the important section perspective views of the wire rod for blood pressure measurement used for the balloon catheter concerning working example of others of this invention.
[0016]As shown in drawing 1, the balloon catheter 20 concerning one working example of this invention has the balloon part 22 expanded and contracted to compensate for the pulsation of the heart. The balloon part 22 comprises a thin film of about about 100-150 micrometers of thickness. Although the construction material in

particular of a thin film is not limited, it is preferred that it is the construction material excellent in the bending-fatigue-resistance characteristic, for example, it is constituted by polyurethane etc. The outer diameter and length of the balloon part 20 are determined as the auxiliary effect of cardiac performance according to the content volume of the balloon part 20 which influences greatly, the inside diameter of an arterial blood pipe, etc. Although the content volume in particular of the balloon part 20 is not limited, it is 30-50 cc.
As for the outer diameter of the balloon part 20, 14-16 mm is preferred, and 210-270 mm of length is preferred.

[0017]The end chip part 25 in which the blood communicating hole 23 is formed is attached to the tip part of this balloon part 22 by thermal melting arrival, adhesion, or other means. The tip part of the inner tube 30 is attached to the inner circumference side of this end chip part 25 by thermal melting arrival, adhesion, or other means. Since the synthetic resin etc. which have flexibility constitute the inner tube 30 from this example so that it may mention later, it may be the structure where the tip of the inner tube 30 serves as the end chip part 25.
[0018]The inner tube 30 extends in shaft orientations, and opens the balloon part 22 and the inside of the catheter tube 24 for free passage to the measuring aperture 32 of the connector 26 mentioned later.
The inside is open for free passage with balloon part 22 inside.

[0019]When the inner tube 30 located in the balloon part 22 inserts the balloon catheter 20 into an artery, it also has the operation as a guide rod at the time of the contracted balloon part 22 being rolled and the balloon part 22 being inserted with sufficient convenience in an artery.
[0020]The tip part of the catheter tube 24 is connected with the rear end part of the balloon part 22 by the periphery side of the metal connection tubes 27. This catheter tube 24 is led, hydrostatic pressure is introduced or drawn in the balloon part 22, and the balloon part 22 expands thru/or contracts. Connection to the balloon part 22 and the catheter tube 24 is performed by adhesion by adhesives, such as thermal melting arrival or ultraviolet curing resin.
[0021]Especially as construction material which constitutes the catheter tube 24, although not limited, polyurethane, polyvinyl chloride, polyethylene, nylon, etc. are used. Although in particular the inside diameter and thickness of the catheter tube 24 are not limited, an inside diameter is 1.5-4.0 mm preferably.
Thickness is 0.05-0.4 mm preferably.

[0022]The connector 26 installed in a patient's outside of the body is connected with the rear end part of the catheter tube 24. Although the connector 26 is fabricated by the catheter tube 24 and the different body and may adhere by thermal melting arrival, adhesion, or other means, it may be fabricated by the catheter tube 24 and one. The pressure flow object introduction exit 28 for introducing or deriving a pressure fluid in the catheter tube 24 and the balloon part 22 and the measuring aperture 32 which is open for free passage in the inner tube 30 are formed in the connector 26.
[0023]The pressure flow object introduction exit 28 is connected to the pumping plant 8 as shown in drawing 6, and hydrostatic pressure is introduced or drawn in the balloon part 22 by this pumping plant 8. Especially as a fluid introduced, although not limited, viscous small gaseous helium etc. are used so that it may respond to the drive of the pumping plant 8 and a balloon part may expand or contract quickly. A device as not limited, for example, shown in JP,H2-39265,B especially as the pumping plant 8 is used.
[0024]At this example, the inner tube 30 consists of construction material which has flexibility. As a flexible pipe which constitutes the inner tube 30, synthetic resin tubes, such as polyurethane, the synthetic resin tube reinforced with the metallic mesh, the tube with which the synthetic resin was laminated on the periphery of the metal spring, etc. are illustrated.
[0025]In the former, direct continuation of the measuring aperture 32 currently formed in the connector 26 to which the rear end part of this inner tube 30 is connected was carried out to the blood-pressure-measurement device, and it had measured change of the blood pressure of the blood in the artery taken in from the blood communicating hole 23 currently formed in the end chip part 25 of the balloon part 22.
[0026]In this example, as shown in drawing 1 and 2 to the measuring aperture 32, the auxiliary connector 40 which has the metal stylette pipe 42 inserted along the inside of the inner tube 30 is connected by screwing connection or other means, and a blood-pressure-measurement device is connected to the blood-pressure-measurement mouth 44 of this auxiliary connector 40. The blood-pressure-measurement mouth 44 of the auxiliary connector 40 is opened for free passage with the inside of the stylette pipe 42. As shown in drawing 3, the tip of the stylette pipe 42 is located in the end chip part 25 of the balloon part 22, and the blood taken in from the blood communicating hole 23 introduces it to the blood-pressure-measurement mouth 44 shown in drawing 2.

[0027]The pulsation of the heart is detected based on change of the blood pressure measured with the blood-pressure-measurement device connected to the blood-pressure-measurement mouth 44, the pumping plant 8 as shown in drawing 6 according to the pulsation of the heart is controlled, and the balloon part 22 is expanded or shrunk.

[0028]Although it is not limited but stainless steel, tungsten, etc. are illustrated especially as metal which constitutes the stylette pipe 42, stainless steel is used preferably. The length of the stylette pipe 42 is in the state where screwing connection of the auxiliary connector 40 was made at the measuring aperture of the connector 26, and as shown in drawing 3, it is designed so that the tip of the stylette pipe 42 may have the buffer distance a which is not protruded from the tip of the end chip part 25. As for the buffer distance a, about 3-30 mm is preferred, for example. The blood communicating hole 23 formed in the end chip part 25 can be formed in a side hole type, it can constitute so that the tip of the end chip part 25 may be blockaded, and the flash of the stylette pipe 42 can also be prevented. A flash is prevented in order to prevent damaging a blood vessel wall etc. by the tip end part of the stylette pipe 42.

[0029]As for the inner diameter dimension, although the outside diameter size in particular of the stylette pipe 42 is not limited, 0.5-0.9 mm is preferred and 0.3-0.75 mm is preferred. As for the inner diameter dimension, although the outside diameter size in particular of the inner tube 30 is not limited, 1.0-1.7 mm is preferred and 0.7-1.1 mm is preferred.

[0030]A crevice arises between the stylette pipe 42 and the inner tube 30, and it is easy to solidify blood in the portion. If the coagulation of blood arises, it will be easy to produce bacterial propagation and will be easy to become causes, such as an infectious disease. It is preferred to form in the auxiliary connector 40 the inlet 46 which is open for free passage in said crevice, to connect the tube 48 and the cross valve 50 to this inlet 46, and to slush blood coagulation prevention liquid into said crevice from the cross valve 50, as such a thing is shown in drawing 1 and 2 as a means to prevent. A heparinization physiological sodium chloride solution etc. are used as a blood coagulation inhibitor. Although the flow in particular is not limited, it is 1 cc/min, for example. Blood coagulation prevention liquid is slushed into a crevice, and it is called flash plate to make a prevention operation of blood perform.

[0031]As the communicating hole 70 which opens the blood-pressure-measurement mouth 44 and the measuring aperture 32 for free passage is formed to the auxiliary connector 40a as shown in drawing 7 (A), or shown in the figure (B), Drawing 1, the cross valve 50 for flash plates shown in 2, and tube 48 grade can also be made unnecessary by establishing the communicating hole 72 in the auxiliary connector side edge part of the stylette pipe 42. Since a flash plate mechanism is generally built into the blood-pressure-measurement circuit connected to the blood-pressure-measurement mouth 44, this can also be used and it is highly convenient. However, it is preferred to use the communicating hole 70 as fine pores in the example shown in drawing 7 (A), and it is preferred that it is the communicating hole 72 which does not make the SUITAI let pipe 42 make it vulnerable in the example shown in the figure (B).

[0032]When inserting the balloon catheter 20 of this example into a blood vessel, in the state where the metal stylette pipe 42 is not inserted into the flexible inner tube 30, the balloon catheter 20 is folded up and it inserts into a blood vessel with the catheter tube 24. In the state where the stiletto pipe 42 is not inserted, it excels in flexibility, and as for the balloon catheter 20, the inside of the blood vessel which wound can be inserted good, without damaging a blood vessel wall.

[0033]After inserting the balloon catheter 20, the stylette pipe 42 is inserted along with the flexible inner tube 30 from the measuring aperture 32 currently formed in the connector 26 installed in the outside of the body. As shown in drawing 3, the tip of the stylette pipe 42 reaches to the end chip part 25 of the balloon part 22 along with flexible inner-tube 30 inside, and makes screwing connection of the auxiliary connector 40 in the state at the connector 26. If a blood-pressure-measurement device is connected to the blood-pressure-measurement mouth 44 of the auxiliary connector 40, a patient's blood can be drawn outside of the body through the inside of the stylette pipe 42, and the blood-pressure change can be measured.

[0034]And since rigidity is high as compared with the flexible inner tube 30, the metal stylette pipe 42, By inserting the stylette pipe 42 into the flexible inner tube 30, the rigidity of the balloon catheter 20 improves, a possibility that the balloon catheter 20 may be ****(ed) by the blood flow decreases, and a kink (break) can also be prevented effectively.

[0035]Since the metal stylette pipe 42 will exist as a secondary operation covering the overall length of the balloon part 22 and the catheter tube 24, if a patient's roentgenography is taken, it will become possible to image the balloon catheter 20 covering an overall length.

[0036]this invention is not limited to working example mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, it is also possible to use the auxiliary connector 60 which has the wire rod 52 for blood pressure measurement used in working example mentioned above as shown in drawing

4 instead of the auxiliary connector 40 with the stylette pipe 42. It has equipped with the pressure sensor 54 at the tip of the wire rod 52 for blood pressure measurement, and it is possible to perceive blood pressure directly. The blood-pressure signal detected with the pressure sensor 54 is sent to the auxiliary connector 60 side through the lead which is not illustrated, and is sent to the code 62 and the plug 64 from there. The plug 64 is electrically connected to a blood-pressure-measurement device.

[0037]It is preferred to stand in a row in a lead and to make the reinforcement wire 58 build in the wire rod 52 for blood pressure measurement only with a lead, since rigidity is generally low. And as for the circumference of the reinforcement wire 58 and a lead, being covered with the resin tube 56 is preferred. The outer diameter and length of the resin tube 56 are comparable as the stylette pipe 42 of working example mentioned above. Especially as the reinforcement wire 58, although not limited, a nickel-Ti alloy wire etc. are used. As for the rigidity as the wire rod 52 whole for blood pressure measurement, it is preferred to become comparable as said stylette pipe 42.

[0038]Like the auxiliary connector 40 which has a stylette pipe of working example mentioned above, after the auxiliary connector 60 which has the wire rod 52 for blood pressure measurement inserts a balloon catheter into a blood vessel, it inserts the wire rod 52 for blood pressure measurement into the inner tube 30, and screwing connection is made at the measuring aperture 32 of the connector 26. Other composition is the same as that of said working example, and it is preferred to slush blood coagulation prevention liquid into the crevice between the wire rod for blood pressure measurement and a flexible inner tube. Since this working example has the same operation as working example mentioned above and he is trying to measure directly the blood-pressure change inside a patient's blood vessel with the pressure sensor 54, its accuracy of measurement improves.

[0039]Drawing 5 shows the modification of working example shown in drawing 4, arranges the spring 66 wound densely around the lead 65 connected to the pressure sensor 54, and constitutes the wire rod 67 for blood pressure measurement to it. Resin is laminated on the periphery of the spring 66 and the inside is sealed on it. With the spring 66, rigidity and elasticity comparable as the wire rod 52 for blood pressure measurement shown in drawing 4 can be obtained.

[0040]

[Effect of the Invention]As explained above, according to this invention, inserting into the blood vessel which wound becomes easy, and after insertion, a blood flow etc. do not ****, but a balloon part is enabled to expand and contract in a normal position, and the effect of the IABP method therapy increases. The danger that a kink (break) etc. will arise in a balloon catheter also decreases.

[Translation done.]

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TECHNICAL FIELD

[Industrial Application]This invention relates to the balloon catheter used for the balloon pumping method in a main artery which are cures, such as acute cardiac insufficiency.

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PRIOR ART

[Description of the Prior Art]The balloon pumping method in a main artery (Intra-aortic balloon pumping and the following call it the "IABP method" for short), For the therapy at the time of the cardiac performance fall of cardiac insufficiency etc., as shown in drawing 6, the balloon catheter 2 which comprises synthetic macromolecule material in a main artery is inserted, It is an auxiliary cycle method which doubles with the pulsation of the heart 1, introduces or draws a pressure fluid from the catheter tube 6 to the balloon part 4 with the pumping plant 8, expands and shrinks the balloon part 4, and assists cardiac performance.
[0003]As a balloon catheter used for the IABP method, the balloon catheter as shown in JP,S63-206255,A and JP,S62-114565,A is known. In such a balloon catheter, in order to double with the pulsation of the heart and to expand and contract a balloon part, it is necessary to detect the pulsation of a patient's heart. As a means to detect the pulsation of a patient's heart, the body surface or inside of a patient is equipped with an electrode, and there is a means to detect the pulsation of the heart as an electrical signal.
[0004]As a means to detect the pulsation of the heart from a patient's blood pressure using a balloon catheter, There is a method of detecting the pulsation of the heart by establishing a blood communicating hole in the end chip part 12 of the balloon part 4 shown in drawing 6, making shaft orientations insert the blood communicating hole and the inner tube 10 open for free passage in the balloon part 4 and the inside of the catheter tube 6, and measuring blood-pressure change from a blood communicating hole.
[0005]When inserting the balloon part 4 and the catheter tube 6 into a patient's arterial blood pipe, a guide wire is inserted into the inner tube 10, and a balloon catheter is inserted along with it. The inner tube 10 also has a function as a guide rod in the case of insertion with a guide wire. Therefore, the inner tube 10 needs to have a certain amount of rigidity. Since a balloon catheter is inserted into the blood vessel of the patient who wound, the inner tube 10 needs to have a certain amount of pliability.
[0006]If the rigidity of the inner tube 10 is too high, while having inserted in the balloon catheter in a patient's blood vessel, it is not desirable from there being a possibility of damaging a patient's blood vessel. If the pliability of the inner tube 10 is too high conversely, when the balloon part 4 will be located in the artery near the pole of the heart 1 and an auxiliary operation of the heart will be performed, It is not desirable from a blood flow **** (ing), and being unable to perform pumping of the balloon part 4 in a regular position, but there being a possibility that an auxiliary operation of the heart may fall, and there being a possibility of blockading the renal artery which branches from an abdominal aorta. It is important for the balloon part 4 to make it located as much as possible in the arterial blood pipe near the heart, and to perform a pumping action.
[0007]From such a viewpoint, a resin tube, a small tube made from stainless steel, etc. which were reinforced with a mesh are used as the conventional inner tube 10.

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EFFECT OF THE INVENTION

[Effect of the Invention]As explained above, according to this invention, inserting into the blood vessel which wound becomes easy, and after insertion, a blood flow etc. do not ****, but a balloon part is enabled to expand and contract in a normal position, and the effect of the IABP method therapy increases. The danger that a kink (break) etc. will arise in a balloon catheter also decreases.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]However, the balloon catheter which has merits and demerits, respectively and is simultaneously satisfied with the balloon catheter using such a conventional inner tube 10 of the insertion nature into the blood vessel which wound, and the rigidity which does not **** to a blood flow and a kink (break) etc. do not produce was called for.
[0009]Measurement of the blood pressure in the blood vessel in which it is made in view of such the actual condition, and a balloon catheter is inserted is possible for this invention, And insertion into the blood vessel which wound is easy, and is not ****(ed) by the blood flow etc. after insertion, but it aims at providing the balloon catheter which a kink (break) etc. do not produce.

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MEANS

[Means for Solving the Problem]To achieve the above objects, a balloon catheter of this invention is provided with the following.
A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed.
A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part.
A flexible inner tube which extends in shaft orientations so that it may be open for free passage to a blood communicating hole established in a tip part of said balloon part and said balloon part and an inside of a catheter tube may not be opened for free passage with a channel of a pressure fluid.
A pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A metal stylette pipe inserted in a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.

[0011]A balloon catheter concerning another viewpoint of this invention is provided with the following.
A balloon part expanded and contracted so that it may be inserted into a main artery and an auxiliary operation of cardiac performance may be performed.
A catheter tube which is connected with the back end of a balloon part, and introduces and derives a pressure fluid in said balloon part.
A flexible inner tube which extends in shaft orientations so that it may be open for free passage to a blood communicating hole established in a tip part of said balloon part and said balloon part and an inside of a catheter tube may not be opened for free passage with a channel of a pressure fluid.
A pressure flow object introduction exit which is connected with the back end of said catheter tube, and introduces and discharges a pressure fluid in a catheter, A wire rod for blood pressure measurement which has a pressure sensor at a connector in which a measuring aperture which is open for free passage inside said flexible inner tube is formed, and a tip inserted in an inside of said flexible inner tube from said measuring aperture to said blood interconnecting opening this side.

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JP,07-024060,A [OPERATION]

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OPERATION

[Function]When inserting the balloon catheter of this invention into a blood vessel, a balloon catheter is inserted into a blood vessel in the state where a metal stylette pipe or wire rod for blood pressure measurement is not inserted into a flexible inner tube. Therefore, it excels in flexibility, and as for a balloon catheter, the inside of the blood vessel which wound can be inserted good, without damaging a blood vessel wall.
[0013]After inserting a balloon catheter, a stylette pipe or the wire rod for blood pressure measurement is inserted along with a flexible inner tube from the measuring aperture currently formed in the connector. The tip of a stylette pipe or the wire rod for blood pressure measurement reaches to the end chip part of a balloon part along with the inside of a flexible inner tube. Therefore, a patient's blood can be drawn outside of the body through the inside of a stylette pipe, and the blood-pressure change can be measured. To the tip part of the wire rod for blood pressure measurement, since the pressure sensor is attached, a direct patient's blood-pressure change can be measured with the pressure sensor.
[0014]And a metal stylette pipe and wire rod for blood pressure measurement, Since rigidity is high as compared with a flexible inner tube, by inserting these any they are into a flexible inner tube, the rigidity of a balloon catheter improves, a possibility that a balloon catheter may be ****(ed) by the blood flow decreases, and a kink (break) can also be prevented effectively.

[Translation done.]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

EXAMPLE

[Example]Hereafter, the balloon catheter concerning this invention is explained in detail based on working example shown in Drawings. The outline sectional view of the balloon catheter which requires drawing 1 for one working example of this invention, the fragmentary sectional view in which drawing 2 shows the important section of the balloon catheter of the working example, The fragmentary sectional view in which drawing 3 shows the important section of others of the working example, the partial fracture perspective view of the wire rod for blood pressure measurement used for the balloon catheter which requires drawing 4 for other working example of this invention, and drawing 5 are the important section perspective views of the wire rod for blood pressure measurement used for the balloon catheter concerning working example of others of this invention.
[0016]As shown in drawing 1, the balloon catheter 20 concerning one working example of this invention has the balloon part 22 expanded and contracted to compensate for the pulsation of the heart. The balloon part 22 comprises a thin film of about about 100-150 micrometers of thickness. Although the construction material in particular of a thin film is not limited, it is preferred that it is the construction material excellent in the bending-fatigue-resistance characteristic, for example, it is constituted by polyurethane etc. The outer diameter and length of the balloon part 20 are determined as the auxiliary effect of cardiac performance according to the content volume of the balloon part 20 which influences greatly, the inside diameter of an arterial blood pipe, etc. Although the content volume in particular of the balloon part 20 is not limited, it is 30-50 cc.
As for the outer diameter of the balloon part 20, 14-16 mm is preferred, and 210-270 mm of length is preferred.

[0017]The end chip part 25 in which the blood communicating hole 23 is formed is attached to the tip part of this balloon part 22 by thermal melting arrival, adhesion, or other means. The tip part of the inner tube 30 is attached to the inner circumference side of this end chip part 25 by thermal melting arrival, adhesion, or other means. Since the synthetic resin etc. which have flexibility constitute the inner tube 30 from this example so that it may mention later, it may be the structure where the tip of the inner tube 30 serves as the end chip part 25.
[0018]The inner tube 30 extends in shaft orientations, and opens the balloon part 22 and the inside of the catheter tube 24 for free passage to the measuring aperture 32 of the connector 26 mentioned later.
The inside is open for free passage with balloon part 22 inside.

[0019]When the inner tube 30 located in the balloon part 22 inserts the balloon catheter 20 into an artery, it also has the operation as a guide rod at the time of the contracted balloon part 22 being rolled and the balloon part 22 being inserted with sufficient convenience in an artery.
[0020]The tip part of the catheter tube 24 is connected with the rear end part of the balloon part 22 by the periphery side of the metal connection tubes 27. This catheter tube 24 is led, hydrostatic pressure is introduced or drawn in the balloon part 22, and the balloon part 22 expands thru/or contracts. Connection to the balloon part 22 and the catheter tube 24 is performed by adhesion by adhesives, such as thermal melting arrival or ultraviolet curing resin.
[0021]Especially as construction material which constitutes the catheter tube 24, although not limited, polyurethane, polyvinyl chloride, polyethylene, nylon, etc. are used. Although in particular the inside diameter and thickness of the catheter tube 24 are not limited, an inside diameter is 1.5-4.0 mm preferably.
Thickness is 0.05-0.4 mm preferably.

[0022]The connector 26 installed in a patient's outside of the body is connected with the rear end part of the catheter tube 24. Although the connector 26 is fabricated by the catheter tube 24 and the different body and may adhere by thermal melting arrival, adhesion, or other means, it may be fabricated by the catheter tube 24 and one. The pressure flow object introduction exit 28 for introducing or deriving a pressure fluid in the catheter

tube 24 and the balloon part 22 and the measuring aperture 32 which is open for free passage in the inner tube 30 are formed in the connector 26.

[0023]The pressure flow object introduction exit 28 is connected to the pumping plant 8 as shown in drawing 6, and hydrostatic pressure is introduced or drawn in the balloon part 22 by this pumping plant 8. Especially as a fluid introduced, although not limited, viscous small gaseous helium etc. are used so that it may respond to the drive of the pumping plant 8 and a balloon part may expand or contract quickly. A device as not limited, for example, shown in JP,H2-39265,B especially as the pumping plant 8 is used.

[0024]At this example, the inner tube 30 consists of construction material which has flexibility. As a flexible pipe which constitutes the inner tube 30, synthetic resin tubes, such as polyurethane, the synthetic resin tube reinforced with the metallic mesh, the tube with which the synthetic resin was laminated on the periphery of the metal spring, etc. are illustrated.

[0025]In the former, direct continuation of the measuring aperture 32 currently formed in the connector 26 to which the rear end part of this inner tube 30 is connected was carried out to the blood-pressure-measurement device, and it had measured change of the blood pressure of the blood in the artery taken in from the blood communicating hole 23 currently formed in the end chip part 25 of the balloon part 22.

[0026]In this example, as shown in drawing 1 and 2 to the measuring aperture 32, the auxiliary connector 40 which has the metal stylette pipe 42 inserted along the inside of the inner tube 30 is connected by screwing connection or other means, and a blood-pressure-measurement device is connected to the blood-pressure-measurement mouth 44 of this auxiliary connector 40. The blood-pressure-measurement mouth 44 of the auxiliary connector 40 is opened for free passage with the inside of the stylette pipe 42. As shown in drawing 3, the tip of the stylette pipe 42 is located in the end chip part 25 of the balloon part 22, and the blood taken in from the blood communicating hole 23 introduces it to the blood-pressure-measurement mouth 44 shown in drawing 2.

[0027]The pulsation of the heart is detected based on change of the blood pressure measured with the blood-pressure-measurement device connected to the blood-pressure-measurement mouth 44, the pumping plant 8 as shown in drawing 6 according to the pulsation of the heart is controlled, and the balloon part 22 is expanded or shrunk.

[0028]Although it is not limited but stainless steel, tungsten, etc. are illustrated especially as metal which constitutes the stylette pipe 42, stainless steel is used preferably. The length of the stylette pipe 42 is in the state where screwing connection of the auxiliary connector 40 was made at the measuring aperture of the connector 26, and as shown in drawing 3, it is designed so that the tip of the stylette pipe 42 may have the buffer distance a which is not protruded from the tip of the end chip part 25. As for the buffer distance a, about 3-30 mm is preferred, for example. The blood communicating hole 23 formed in the end chip part 25 can be formed in a side hole type, it can constitute so that the tip of the end chip part 25 may be blockaded, and the flash of the stylette pipe 42 can also be prevented. A flash is prevented in order to prevent damaging a blood vessel wall etc. by the tip end part of the stylette pipe 42.

[0029]As for the inner diameter dimension, although the outside diameter size in particular of the stylette pipe 42 is not limited, 0.5-0.9 mm is preferred and 0.3-0.75 mm is preferred. As for the inner diameter dimension, although the outside diameter size in particular of the inner tube 30 is not limited, 1.0-1.7 mm is preferred and 0.7-1.1 mm is preferred.

[0030]A crevice arises between the stylette pipe 42 and the inner tube 30, and it is easy to solidify blood in the portion. If the coagulation of blood arises, it will be easy to produce bacterial propagation and will be easy to become causes, such as an infectious disease. It is preferred to form in the auxiliary connector 40 the inlet 46 which is open for free passage in said crevice, to connect the tube 48 and the cross valve 50 to this inlet 46, and to slush blood coagulation prevention liquid into said crevice from the cross valve 50, as such a thing is shown in drawing 1 and 2 as a means to prevent. A heparinization physiological sodium chloride solution etc. are used as a blood coagulation inhibitor. Although the flow in particular is not limited, it is 1 cc/min, for example. Blood coagulation prevention liquid is slushed into a crevice, and it is called flash plate to make a prevention operation of blood perform.

[0031]As the communicating hole 70 which opens the blood-pressure-measurement mouth 44 and the measuring aperture 32 for free passage is formed to the auxiliary connector 40a as shown in drawing 7 (A), or shown in the figure (B), Drawing 1, the cross valve 50 for flash plates shown in 2, and tube 48 grade can also be made unnecessary by establishing the communicating hole 72 in the auxiliary connector side edge part of the stylette pipe 42. Since a flash plate mechanism is generally built into the blood-pressure-measurement circuit connected to the blood-pressure-measurement mouth 44, this can also be used and it is highly convenient. However, it is preferred to use the communicating hole 70 as fine pores in the example shown in drawing 7 (A), and it is preferred that it is the communicating hole 72 which does not make the SUITAI let pipe 42 make it

vulnerable in the example shown in the figure (B).
[0032]When inserting the balloon catheter 20 of this example into a blood vessel, in the state where the metal stylette pipe 42 is not inserted into the flexible inner tube 30, the balloon catheter 20 is folded up and it inserts into a blood vessel with the catheter tube 24. In the state where the stiletto pipe 42 is not inserted, it excels in flexibility, and as for the balloon catheter 20, the inside of the blood vessel which wound can be inserted good, without damaging a blood vessel wall.
[0033]After inserting the balloon catheter 20, the stylette pipe 42 is inserted along with the flexible inner tube 30 from the measuring aperture 32 currently formed in the connector 26 installed in the outside of the body. As shown in drawing 3, the tip of the stylette pipe 42 reaches to the end chip part 25 of the balloon part 22 along with flexible inner-tube 30 inside, and makes screwing connection of the auxiliary connector 40 in the state at the connector 26. If a blood-pressure-measurement device is connected to the blood-pressure-measurement mouth 44 of the auxiliary connector 40, a patient's blood can be drawn outside of the body through the inside of the stylette pipe 42, and the blood-pressure change can be measured.
[0034]And since rigidity is high as compared with the flexible inner tube 30, the metal stylette pipe 42, By inserting the stylette pipe 42 into the flexible inner tube 30, the rigidity of the balloon catheter 20 improves, a possibility that the balloon catheter 20 may be ****(ed) by the blood flow decreases, and a kink (break) can also be prevented effectively.
[0035]Since the metal stylette pipe 42 will exist as a secondary operation covering the overall length of the balloon part 22 and the catheter tube 24, if a patient's roentgenography is taken, it will become possible to image the balloon catheter 20 covering an overall length.
[0036]this invention is not limited to working example mentioned above, within the limits of this invention, can be boiled variously and can be changed. For example, it is also possible to use the auxiliary connector 60 which has the wire rod 52 for blood pressure measurement used in working example mentioned above as shown in drawing 4 instead of the auxiliary connector 40 with the stylette pipe 42. It has equipped with the pressure sensor 54 at the tip of the wire rod 52 for blood pressure measurement, and it is possible to perceive blood pressure directly. The blood-pressure signal detected with the pressure sensor 54 is sent to the auxiliary connector 60 side through the lead which is not illustrated, and is sent to the code 62 and the plug 64 from there. The plug 64 is electrically connected to a blood-pressure-measurement device.
[0037]It is preferred to stand in a row in a lead and to make the reinforcement wire 58 build in the wire rod 52 for blood pressure measurement only with a lead, since rigidity is generally low. And as for the circumference of the reinforcement wire 58 and a lead, being covered with the resin tube 56 is preferred. The outer diameter and length of the resin tube 56 are comparable as the stylette pipe 42 of working example mentioned above. Especially as the reinforcement wire 58, although not limited, a nickel-Ti alloy wire etc. are used. As for the rigidity as the wire rod 52 whole for blood pressure measurement, it is preferred to become comparable as said stylette pipe 42.
[0038]Like the auxiliary connector 40 which has a stylette pipe of working example mentioned above, after the auxiliary connector 60 which has the wire rod 52 for blood pressure measurement inserts a balloon catheter into a blood vessel, it inserts the wire rod 52 for blood pressure measurement into the inner tube 30, and screwing connection is made at the measuring aperture 32 of the connector 26. Other composition is the same as that of said working example, and it is preferred to slush blood coagulation prevention liquid into the crevice between the wire rod for blood pressure measurement and a flexible inner tube. Since this working example has the same operation as working example mentioned above and he is trying to measure directly the blood-pressure change inside a patient's blood vessel with the pressure sensor 54, its accuracy of measurement improves.
[0039]Drawing 5 shows the modification of working example shown in drawing 4, arranges the spring 66 wound densely around the lead 65 connected to the pressure sensor 54, and constitutes the wire rod 67 for blood pressure measurement to it. Resin is laminated on the periphery of the spring 66 and the inside is sealed on it. With the spring 66, rigidity and elasticity comparable as the wire rod 52 for blood pressure measurement shown in drawing 4 can be obtained.

[Translation done.]

* NOTICES *

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]It is an outline sectional view of the balloon catheter concerning one working example of this invention.
[Drawing 2]It is a fragmentary sectional view showing the important section of the balloon catheter of the working example.
[Drawing 3]It is a fragmentary sectional view showing the important section of others of the working example.
[Drawing 4]It is a partial fracture perspective view of the wire rod for blood pressure measurement used for the balloon catheter concerning other working example of this invention.
[Drawing 5]It is an important section perspective view of the wire rod for blood pressure measurement used for the balloon catheter concerning working example of others of this invention.
[Drawing 6]It is a schematic diagram explaining the directions for a balloon catheter.
[Drawing 7]It is an important section sectional view of an auxiliary connector used in other working example of this invention.
[Description of Notations]
20 -- Balloon catheter
22 -- Balloon part
23 -- Blood communicating hole
24 -- Catheter tube
25 -- End chip part
26 -- Connector
28 -- Pressure flow object introduction exit
30 -- Flexible inner tube
32 -- Measuring aperture
40, 60 -- Auxiliary connector
42 -- Stylette pipe
44 -- Blood-pressure-measurement mouth
52, 67 -- Wire rod for blood pressure measurement
54 -- Pressure sensor

[Translation done.]

* NOTICES *

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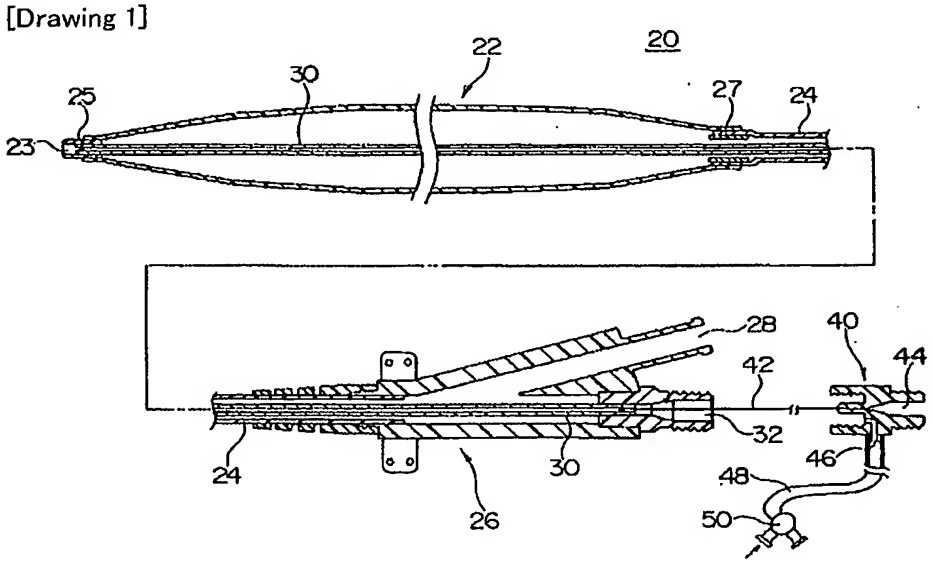
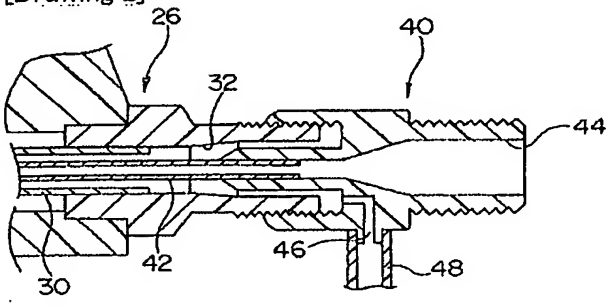
3.In the drawings, any words are not translated.

DRAWINGS

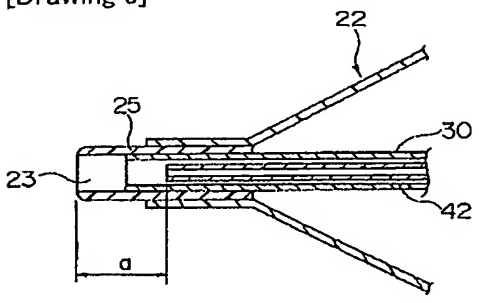
[Drawing 1]



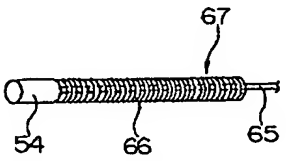
[Drawing 2]



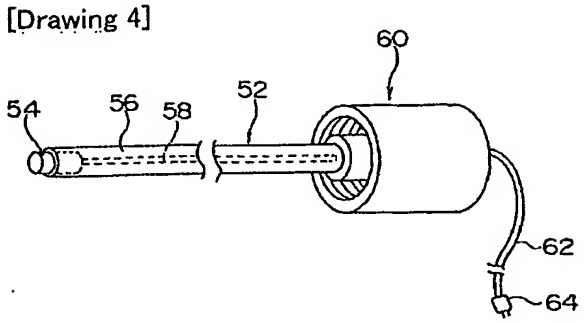
[Drawing 3]



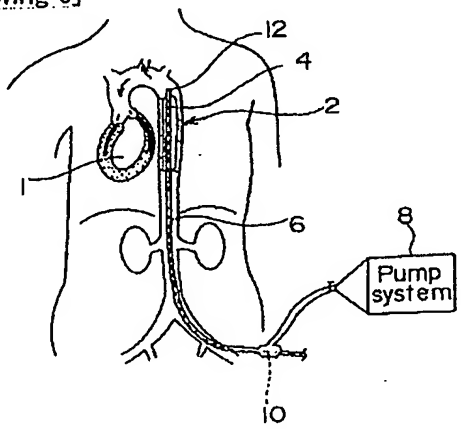
[Drawing 5]



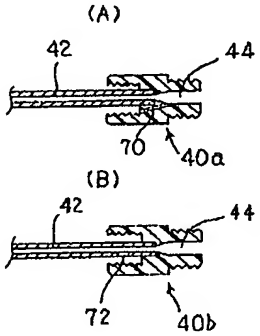
[Drawing 4]



[Drawing 6]



[Drawing 7]



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Ａ６１Ｂ　5/022				
Ａ６１Ｍ　25/00				
		7638－4C	Ａ６１Ｂ　5/ 02　３３７　Ａ	
		9052－4C	Ａ６１Ｍ　25/ 00　４１０　Ｆ	

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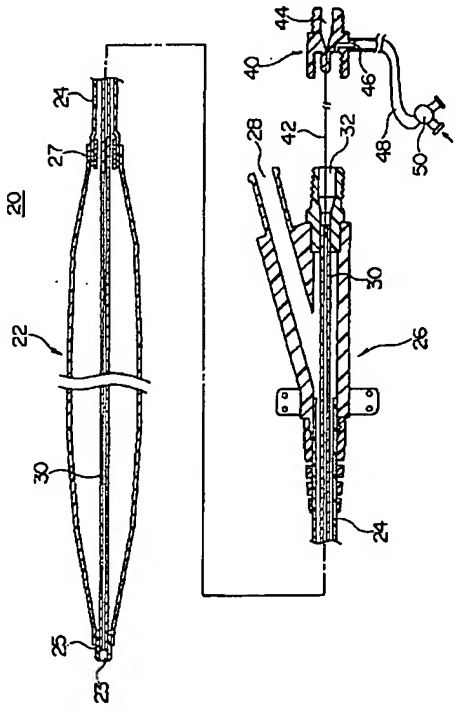
(54)【発明の名称】　バルーンカテーテル

(57)【要約】　（修正有）

【目的】　挿入後には、血流などにより押戻されず、キンク（折れ）などが生じない血圧の測定用バルーンカテーテルを提供する。

【構成】　バルーンカテーテル２０は、大動脈内に挿入されて、心機能の補助作用を行うように膨張および収縮するバルーン部２２と、バルーン部２２内に圧力流体を導入および導出するカテーテル管２４と、バルーン部２２の先端部に設けられた血液連通孔２３に連通し、バルーン部２２およびカテーテル管２４内部を、軸方向に延在する可撓性内管３０とを有する。カテーテル管２４の後端には、圧力流体導入出口２８と、測定口３２とが形成してあるコネクタ２６が連結される。バルーンカテーテルが血管内に挿入された後には、可撓性内管３０の内部に、測定口３２から血液連通孔２３手前まで金属製のスタイレット管４２が挿入される。



1

【特許請求の範囲】

【請求項１】　大動脈内に挿入されて、心機能の補助作用を行うように膨張および収縮するバルーン部と、
バルーン部の後端に連結されて、前記バルーン部内に圧力流体を導入および導出するカテーテル管と、
前記バルーン部の先端部に設けられた血液連通孔に連通し、前記バルーン部およびカテーテル管内部を、圧力流体の流路と連通しないように、軸方向に延在する可撓性内管と、
前記カテーテル管の後端に連結され、圧力流体をカテーテル内に導入および排出する圧力流体導入出口と、前記可撓性内管の内部に連通する測定口とが形成してあるコネクタと、
前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入される金属製のスタイレット管とを有するバルーンカテーテル。

【請求項２】　前記スタイレット管は、バルーン部およびカテーテル管が血管内に挿入された後、前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入されることを特徴とする請求項１に記載のバルーンカテーテル。

【請求項３】　前記スタイレット管および前記可撓性内管の隙間に、血流の凝固を防止するための液体を供給するフラッシュ手段を有する請求項１または２に記載のバルーンカテーテル。

【請求項４】　大動脈内に挿入されて、心機能の補助作用を行うように膨張および収縮するバルーン部と、
バルーン部の後端に連結されて、前記バルーン部内に圧力流体を導入および導出するカテーテル管と、
前記バルーン部の先端部に設けられた血液連通孔に連通し、前記バルーン部およびカテーテル管内部を、圧力流体の流路と連通しないように、軸方向に延在する可撓性内管と、
前記カテーテル管の後端に連結され、圧力流体をカテーテル内に導入および排出する圧力流体導入出口と、前記可撓性内管の内部に連通する測定口とが形成してあるコネクタと、
前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入される先端に圧力センサを有する血圧測定用線材とを有するバルーンカテーテル。

【請求項５】　前記血圧測定用線材は、バルーン部およびカテーテル管が血管内に挿入された後、前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入されることを特徴とする請求項４に記載のバルーンカテーテル。

【請求項６】　前記血圧測定用線材および前記可撓性内管の隙間に、血流の凝固を防止するための液体を供給するフラッシュ手段を有する請求項４または５に記載のバルーンカテーテル。

【発明の詳細な説明】

2

【０００１】

【産業上の利用分野】本発明は、急性心不全等の治療法である大動脈内バルーンポンピング法に用いるバルーンカテーテルに関する。

【０００２】

【従来の技術】大動脈内バルーンポンピング法（Intra-aortic balloon pumping，以下、「IABP法」と略称する）とは、心不全等の心機能低下時の治療のため、図６に示すように、大動脈内に合成高分子材から成るバルーンカテーテル２を挿入し、心臓１の拍動に合わせてポンプ装置８によりカテーテル管６からバルーン部４に圧力流体を導入または導出し、バルーン部４を膨張・収縮させて心機能の補助を行う補助循環方法である。

【０００３】IABP法に用いられるバルーンカテーテルとしては、特開昭６３－２０６２５５号公報および特開昭６２－１１４５６５号公報に示すようなバルーンカテーテルが知られている。このようなバルーンカテーテルにおいて、心臓の拍動に合わせてバルーン部を膨張および収縮するために、患者の心臓の拍動を検知する必要がある。患者の心臓の拍動を検知する手段として、患者の体表面あるいは内部に電極を装着し、心臓の拍動を電気信号として検出する手段がある。

【０００４】また、バルーンカテーテルを利用して患者の血圧から心臓の拍動を検出する手段として、図６に示すバルーン部４の先端チップ部１２に、血液連通孔を設け、その血液連通孔と連通する内管１０を、バルーン部４およびカテーテル管６の内部に軸方向に挿通させ、血液連通孔から血圧変動を測定することにより、心臓の拍動を検出する方法がある。

【０００５】バルーン部４およびカテーテル管６を、患者の動脈血管内に挿入する際には内管１０内にガイドワイヤーを挿入し、それに沿ってバルーンカテーテルを挿入する。内管１０は、ガイドワイヤーと共に、挿入の際の案内ロッドとしての機能も有する。したがって、内管１０は、ある程度の剛性を有する必要がある。また、バルーンカテーテルは、曲がりくねった患者の血管内に挿入されることから、内管１０は、ある程度の柔軟性を有する必要がある。

【０００６】内管１０の剛性が余りに高いと、バルーンカテーテルを患者の血管内に挿通している間に、患者の血管を傷つけるおそれがあることから好ましくない。また、逆に、内管１０の柔軟性が余りに高いと、バルーン部４を心臓１の極近くの動脈内に位置させて心臓の補助作用を行なう際に、血流により押戻され、正規の位置でバルーン部４のポンピングを行なうことができず、心臓の補助作用が低下するおそれがあるし、腹部大動脈から分岐する腎動脈を閉塞するおそれがあることから好ましくない。バルーン部４は、できるだけ心臓の近くの動脈血管内に位置させて、ポンピング作用を行なうことが重要である。

【０００７】このような観点から、従来の内管１０としては、メッシュで補強された樹脂チューブやステンレス製細管などが用いられている。

【０００８】

【発明が解決しようとする課題】しかしながら、このような従来の内管１０を用いたバルーンカテーテルでは、それぞれ一長一短を有し、曲がりくねった血管内への挿入性と、血流に対して押戻されずキンク（折れ）などが生じない剛性とを同時に満足するバルーンカテーテルが求められていた。

【０００９】本発明は、このような実情に鑑みてなされ、バルーンカテーテルが挿入される血管内の血圧の測定が可能であり、しかも、曲がりくねった血管内への挿入が容易であり、かつ、挿入後には、血流などにより押戻されず、キンク（折れ）などが生じないバルーンカテーテルを提供することを目的とする。

【００１０】

【課題を解決するための手段】上記目的を達成するために、本発明のバルーンカテーテルは、大動脈内に挿入されて、心機能の補助作用を行うように膨張および収縮するバルーン部と、バルーン部の後端に連結されて、前記バルーン部内に圧力流体を導入および導出するカテーテル管と、前記バルーン部の先端部に設けられた血液連通孔に連通し、前記バルーン部およびカテーテル管内部を、圧力流体の流路と連通しないように、軸方向に延在する可撓性内管と、前記カテーテル管の後端に連結され、圧力流体をカテーテル内に導入および排出する圧力流体導入出口と、前記可撓性内管の内部に連通する測定口とが形成してあるコネクタと、前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入される金属製のスタイレット管とを有する。

【００１１】また、本発明の別の観点に係るバルーンカテーテルは、大動脈内に挿入されて、心機能の補助作用を行うように膨張および収縮するバルーン部と、バルーン部の後端に連結されて、前記バルーン部内に圧力流体を導入および導出するカテーテル管と、前記バルーン部の先端部に設けられた血液連通孔に連通し、前記バルーン部およびカテーテル管内部を、圧力流体の流路と連通しないように、軸方向に延在する可撓性内管と、前記カテーテル管の後端に連結され、圧力流体をカテーテル内に導入および排出する圧力流体導入出口と、前記可撓性内管の内部に連通する測定口とが形成してあるコネクタと、前記可撓性内管の内部に、前記測定口から前記血液連通口手前まで挿入される先端に圧力センサを有する血圧測定用線材とを有する。

【００１２】

【作用】本発明のバルーンカテーテルを血管内に挿入する際には、可撓性内管内に金属製のスタイレット管または血圧測定用線材を挿入しない状態で、バルーンカテーテルを血管内に挿入する。したがって、バルーンカテーテルは可撓性に優れており、曲がりくねった血管内を、血管内壁を傷つけることなく良好に挿入することができる。

【００１３】バルーンカテーテルを挿入した後には、コネクタに形成してある測定口から、スタイレット管または血圧測定用線材を可撓性内管に沿って挿入する。スタイレット管または血圧測定用線材の先端は、可撓性内管内部に沿ってバルーン部の先端チップ部まで到達する。したがって、スタイレット管の内部を通して患者の血液を体外に導出し、その血圧変動を測定することができる。また、血圧測定用線材の先端部には、圧力センサが取り付けてあることから、その圧力センサにより直接患者の血圧変動を測定することができる。

【００１４】そして、金属製のスタイレット管および血圧測定用線材は、可撓性内管に比較して剛性が高いので、これらの何れかを可撓性内管内に挿入することで、バルーンカテーテルの剛性が向上し、バルーンカテーテルが血流により押戻されるおそれが減少し、キンク（折れ）も有効に防止できる。

【００１５】

【実施例】以下、本発明に係るバルーンカテーテルについて、図面に示す実施例に基づき詳細に説明する。図１は本発明の一実施例に係るバルーンカテーテルの概略断面図、図２は同実施例のバルーンカテーテルの要部を示す部分断面図、図３は同実施例のその他の要部を示す部分断面図、図４は本発明の他の実施例に係るバルーンカテーテルに用いる血圧測定用線材の一部破断斜視図、図５は本発明のその他の実施例に係るバルーンカテーテルに用いる血圧測定用線材の要部斜視図である。

【００１６】図１に示すように、本発明の一実施例に係るバルーンカテーテル２０は、心臓の拍動に合わせて膨張および収縮するバルーン部２２を有する。バルーン部２２は、膜厚約１００～１５０μｍ程度の薄膜で構成される。薄膜の材質は、特に限定されないが、耐屈曲疲労特性に優れた材質であることが好ましく、例えばポリウレタンなどにより構成される。バルーン部２０の外径および長さは、心機能の補助効果に大きく影響するバルーン部２０の内容積と、動脈血管の内径などに応じて決定される。バルーン部２０の内容積は、特に限定されないが、３０～５０ｃｃであり、バルーン部２０の外径は、１４～１６ｍｍが好ましく、長さは、２１０～２７０ｍｍが好ましい。

【００１７】このバルーン部２２の先端部には、血液連通孔２３が形成してある先端チップ部２５が熱融着ないしは接着などの手段で取り付けてある。この先端チップ部２５の内周側には、内管３０の先端部が熱融着ないしは接着などの手段で取り付けてある。本実施例では、後述するように、内管３０を可撓性を有する合成樹脂などで構成することから、内管３０の先端が先端チップ部２５を兼ねるような構造であっても良い。

【００１８】内管３０は、バルーン部２２およびカテーテル管２４の内部を軸方向に延在し、後述するコネクタ２６の測定口３２に連通するようになっており、その内部は、バルーン部２２内部とは連通しないようになっている。

【００１９】バルーン部２２内に位置する内管３０は、バルーンカテーテル２０を動脈内に挿入する際に、収縮したバルーン部２２が巻かれてバルーン部２２が都合良く動脈内に差し込まれる際の案内ロッドとしての作用も有する。

【００２０】バルーン部２２の後端部には、金属製の接続チューブ２７の外周側で、カテーテル管２４の先端部が連結してある。このカテーテル管２４を通じて、バルーン部２２内に、流体圧が導入または導出され、バルーン部２２が膨張ないし収縮するようになっている。バルーン部２２とカテーテル管２４との連結は、熱融着あるいは紫外線硬化樹脂などの接着剤による接着により行われる。

【００２１】カテーテル管２４を構成する材質としては、特に限定されないが、ポリウレタン、ポリ塩化ビニル、ポリエチレン、ナイロン等が用いられる。また、カテーテル管２４の内径および肉厚は、特に限定されないが、内径は、好ましくは、１．５～４．０㎜であり、肉厚は、好ましくは、０．０５～０．４㎜である。

【００２２】カテーテル管２４の後端部には、患者の体外に設置されるコネクタ２６が連結してある。コネクタ２６は、カテーテル管２４と別体に成形され、熱融着あるいは接着などの手段で固着されても良いが、カテーテル管２４と一体に成形されても良い。コネクタ２６には、カテーテル管２４およびバルーン部２２内に圧力流体を導入または導出するための圧力流体導入出口２８と、内管３０内に連通する測定口３２とが形成してある。

【００２３】圧力流体導入出口２８は、図６に示すようなポンプ装置８に接続され、このポンプ装置８により、流体圧がバルーン部２２内に導入または導出されるようになっている。導入される流体としては、特に限定されないが、ポンプ装置８の駆動に応じて素早くバルーン部が膨張または収縮するように、粘性の小さいヘリウムガスなどが用いられる。また、ポンプ装置８としては、特に限定されず、例えば特公平２－３９２６５号公報に示すような装置が用いられる。

【００２４】本実施例では、内管３０を、可撓性を有する材質で構成する。内管３０を構成する可撓性管としては、ポリウレタンなどの合成樹脂チューブ、金属メッシュで補強された合成樹脂チューブ、金属スプリングの外周に合成樹脂が被着されたチューブなどが例示される。

【００２５】この内管３０の後端部が接続されるコネクタ２６に形成してある測定口３２は、従来では、血圧測定装置に直接接続され、バルーン部２２の先端チップ部２５に形成してある血液連通孔２３から取り入れた動脈内の血液の血圧の変動を測定していた。

【００２６】本実施例では、測定口３２に対して、図１，２に示すように、内管３０内に沿って挿入される金属製のスタイレット管４２を有する補助コネクタ４０が螺合接続などの手段で連結され、この補助コネクタ４０の血圧測定口４４に対して血圧測定装置が接続される。補助コネクタ４０の血圧測定口４４は、スタイレット管４２の内部と連通してある。スタイレット管４２の先端は、図３に示すように、バルーン部２２の先端チップ部２５内に位置し、血液連通孔２３から取り入れた血液が図２に示す血圧測定口４４まで導入するようになっている。

【００２７】血圧測定口４４に接続される血圧測定装置で測定した血圧の変動に基づき、心臓の拍動を検出し、心臓の拍動に応じて図６に示すようなポンプ装置８を制御し、バルーン部２２を膨張または収縮させる。

【００２８】スタイレット管４２を構成する金属としては、特に限定されず、ステンレス、タングステンなどが例示されるが、好ましくはステンレスが用いられる。スタイレット管４２の長さは、補助コネクタ４０がコネクタ２６の測定口に螺合接続された状態で、図３に示すように、スタイレット管４２の先端が、先端チップ部２５の先端からはみ出さない余裕距離ａを持つように設計される。余裕距離ａは、たとえば３～３０㎜程度が好ましい。なお、先端チップ部２５に形成する血液連通孔２３を横孔式に形成し、先端チップ部２５の先端を閉塞するように構成し、スタイレット管４２のはみ出しを防止することもできる。はみ出しを防止するのは、スタイレット管４２の先端部分により血管内壁などを傷つけるのを防止するためである。

【００２９】スタイレット管４２の外径寸法は、特に限定されないが、０．５～０．９㎜が好ましく、その内径寸法は、０．３～０．７５㎜が好ましい。また、内管３０の外径寸法は、特に限定されないが、１．０～１．７㎜が好ましく、その内径寸法は、０．７～１．１㎜が好ましい。

【００３０】スタイレット管４２と内管３０との間には隙間が生じ、その部分では血液が凝固し易い。血液の凝固が生じると、細菌の繁殖が生じ易く、感染症等の原因となり易い。このようなことを防ぐ手段として図１，２に示すように、補助コネクタ４０には、前記隙間に連通する注入口４６を形成し、この注入口４６にチューブ４８および三方弁５０を接続し、三方弁５０から血液凝固防止液を前記隙間へ流し込むことが好ましい。血液凝固防止剤としては、ヘパリン化生食液などが用いられる。その流量は、特に限定されないが、たとえば１cc/minである。隙間へ血液凝固防止液を流し込み、血液の防止作用を行わせることをフラッシュと言う。

【００３１】なお、図７（Ａ）に示すように、補助コネ

クタ４０ａに対して、血圧測定口４４と測定口３２とを連通する連通孔７０を設けたり、同図（Ｂ）に示すように、スタイレット管４２の補助コネクタ側端部に、連通孔７２を設けることで、図１，２に示すフラッシュ用三方弁５０およびチューブ４８等を不要にすることもできる。一般に、血圧測定口４４に接続される血圧測定回路には、フラッシュ機構が組み込まれるため、これも利用でき至便である。ただし、図７（Ａ）に示す例では、連通孔７０を細孔にすることが好ましく、同図（Ｂ）に示す例ではスイタイレット管４２をぜい弱化させないような連通孔７２であることが好ましい。

【００３２】本実施例のバルーンカテーテル２０を血管内に挿入する際には、可撓性内管３０内に金属製のスタイレット管４２を挿入しない状態で、バルーンカテーテル２０を折り畳んでカテーテル管２４と共に、血管内に挿入する。ステイレット管４２を挿入しない状態では、バルーンカテーテル２０は可撓性に優れており、曲がりくねった血管内を、血管内壁を傷つけることなく良好に挿入することができる。

【００３３】バルーンカテーテル２０を挿入した後には、体外に設置されたコネクタ２６に形成してある測定口３２から、スタイレット管４２を可撓性内管３０に沿って挿入する。スタイレット管４２の先端は、図３に示すように、可撓性内管３０内部に沿ってバルーン部２２の先端チップ部２５まで到達し、その状態で補助コネクタ４０をコネクタ２６に螺合接続する。補助コネクタ４０の血圧測定口４４に血圧測定装置を接続すれば、スタイレット管４２の内部を通して患者の血液を体外に導出し、その血圧変動を測定することができる。

【００３４】そして、金属製のスタイレット管４２は、可撓性内管３０に比較して剛性が高いので、スタイレット管４２を可撓性内管３０内に挿入することで、バルーンカテーテル２０の剛性が向上し、バルーンカテーテル２０が血流により押戻されるおそれが減少し、キンク（折れ）も有効に防止できる。

【００３５】また、副次的な作用として、バルーン部２２およびカテーテル管２４の全長にわたり、金属製のスタイレット管４２が存在することになるので、患者のレントゲン写真を撮れば、バルーンカテーテル２０を全長にわたり造影することが可能になる。

【００３６】なお、本発明は、上述した実施例に限定されるものではなく、本発明の範囲内で種々に改変することができる。たとえば上述した実施例で用いるスタイレット管４２付補助コネクタ４０の代わりに、図４に示すような血圧測定用線材５２を有する補助コネクタ６０を用いることも可能である。血圧測定用線材５２の先端には、圧力センサ５４が装着してあり、血圧を直接感知することが可能である。圧力センサ５４で検知した血圧信号は、図示しないリード線を通して補助コネクタ６０側へ送られ、そこから、コード６２およびプラグ６４へ送られる。プラグ６４は、血圧測定装置に電気的に接続される。

【００３７】リード線だけでは、一般に剛性が低いので、リード線に並列して補強ワイヤ５８を血圧測定用線材５２に内蔵させることが好ましい。そして、補強ワイヤ５８およびリード線の周囲は、樹脂チューブ５６で覆われていることが好ましい。樹脂チューブ５６の外径および長さは、前述した実施例のスタイレット管４２と同程度である。補強ワイヤ５８としては、特に限定されないが、Ｎｉ－Ｔｉ合金ワイヤなどが用いられる。血圧測定用線材５２全体としての剛性は、前記スタイレット管４２と同程度となることが好ましい。

【００３８】血圧測定用線材５２を有する補助コネクタ６０は、前述した実施例のスタイレット管を有する補助コネクタ４０と同様に、バルーンカテーテルを血管内に挿入した後、内管３０内に血圧測定用線材５２を挿入し、コネクタ２６の測定口３２に螺合接続される。その他の構成は、前記実施例と同様であり、血圧測定用線材と可撓性内管の隙間に、血液凝固防止液を流し込むことが好ましい。この実施例は、前述した実施例と同様な作用を有すると共に、圧力センサ５４により患者の血管内部の血圧変化を直接測定するようにしているので、測定精度が向上する。

【００３９】図５は、図４に示す実施例の変形例を示し、圧力センサ５４に接続されるリード線６５の周囲に、密に巻回されたスプリング６６を配置し、血圧測定用線材６７を構成している。スプリング６６の外周には、樹脂が被着してあり、内部を密封している。スプリング６６により、図４に示す血圧測定用線材５２と同程度の剛性および弾力性を得ることができる。

【００４０】

【発明の効果】以上説明してきたように、本発明によれば、曲がりくねった血管内への挿入が容易となり、かつ、挿入後には、血流などにより押戻されず、バルーン部が正常な位置で膨張および収縮することが可能になり、ＩＡＢＰ法治療の効果が増大する。また、バルーンカテーテルにキンク（折れ）などが生じる危険性も減少する。

【図面の簡単な説明】

【図１】本発明の一実施例に係るバルーンカテーテルの概略断面図である。

【図２】同実施例のバルーンカテーテルの要部を示す部分断面図である。

【図３】同実施例のその他の要部を示す部分断面図である。

【図４】本発明の他の実施例に係るバルーンカテーテルに用いる血圧測定用線材の一部破断斜視図である。

【図５】本発明のその他の実施例に係るバルーンカテーテルに用いる血圧測定用線材の要部斜視図である。

【図６】バルーンカテーテルの使用方法を説明する概略

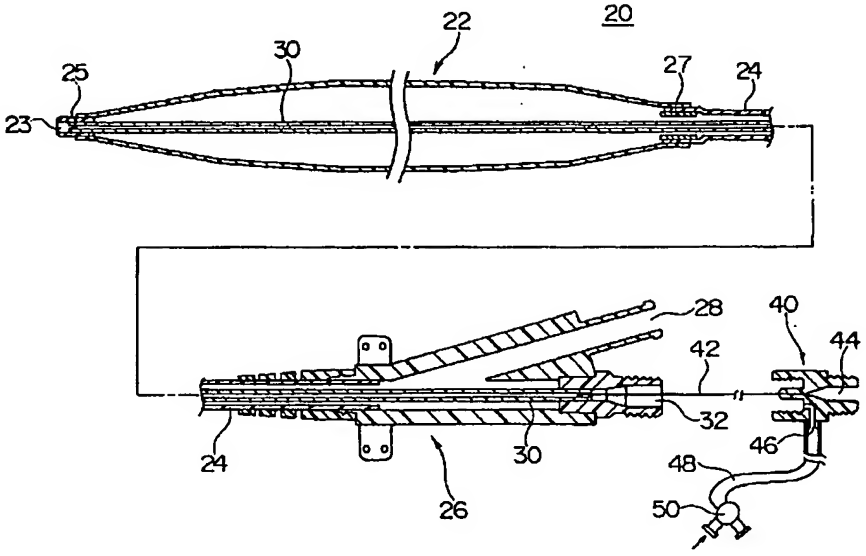
図である。

【図７】本発明の他の実施例で用いる補助コネクタの要部断面図である。

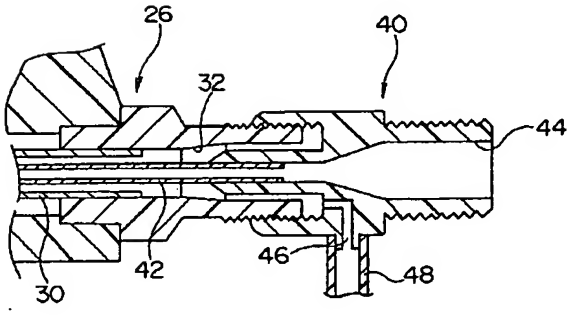
【符号の説明】

２０…　バルーンカテーテル
２２…　バルーン部
２３…　血液連通孔
２４…　カテーテル管
２５…　先端チップ部
＊２６…　コネクタ
２８…　圧力流体導入出口
３０…　可撓性内管
３２…　測定口
４０，６０…　補助コネクタ
４２…　スタイレット管
４４…　血圧測定口
５２，６７…　血圧測定用線材
＊５４…　圧力センサ

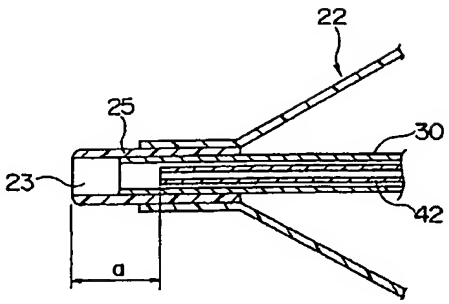
【図１】



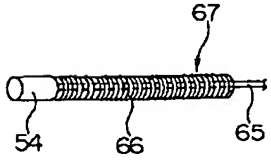
【図２】



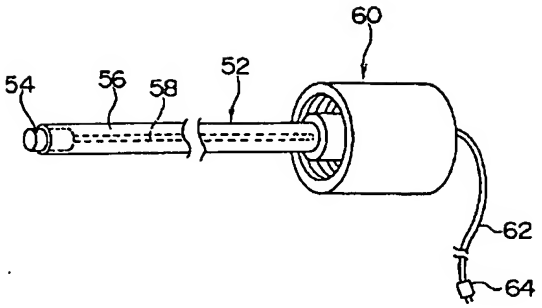
【図３】



【図５】



【図4】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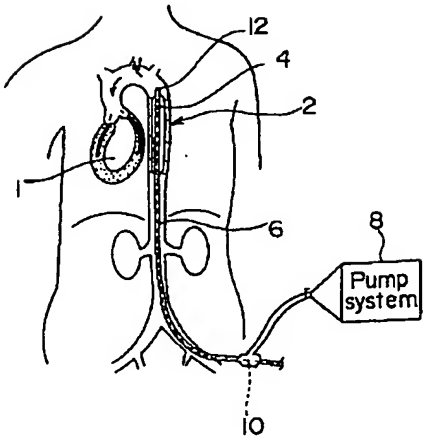
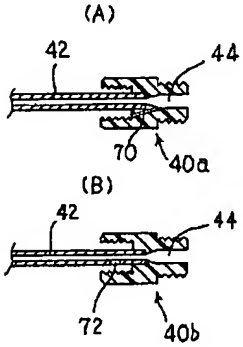
54
56
58
52
62
64

【図6】


12
4
2
1
6
8
Pump system
10

【図7】


(A)
42
44
70
40a
(B)
42
44
72
40b